4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA-2016-N-1487]

Electronic Import Entries; Technical Amendments

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is amending its electronic import entries regulation to correct the statutory citation in the sections of that regulation requiring submission of the Drug Registration Number for human drugs and for animal drugs. The present revisions are necessary to correct editorial errors and to ensure that the codified cites the correct section of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The electronic import entries regulation provides that the Drug Registration Number, which must be submitted at the time of entry in the Automated Commercial Environment (ACE) or any other electronic data interchange (EDI) system authorized by the U.S. Customs and Border Protection Agency (CBP), is the unique facility identifier specified in the FD&C Act. This rule does not impose any new regulatory requirements on affected parties. This action is editorial in nature and is intended to improve the accuracy of the Agency's regulations.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: For access to the docket to read background documents or comments received, go to https://www.regulations.gov and insert the docket number found in brackets in the heading of this final rule into the "Search" box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Ann Metayer, Office of Regulatory Affairs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4375, Silver Spring, MD 20903-0002, 301-796-3324, Ann.Metayer@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the *Federal Register* of November 29, 2016 (81 FR 85854), FDA published a final rule that established requirements for the electronic filing of entries for FDA-regulated products in the ACE or any other EDI system authorized by the CBP. The rule requires the submission of the Drug Registration Number for human and animal drugs in ACE at the time of entry. The Drug Registration Number that must be submitted at the time of entry in ACE is the unique facility identifier of the foreign establishment where the human or animal drug was manufactured, prepared, propagated, compounded, or processed before being imported or offered for import into the United States. The unique facility identifier is the identifier submitted by a registrant in accordance with the system specified under section 510 of the FD&C Act (21 U.S.C. 360).

II. Description of the Technical Amendments

We are amending the electronic import entries regulation to revise the statutory citation in the sections of that rule requiring submission of the Drug Registration Number for human drugs regulated by FDA's Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research, and for animal drugs regulated by FDA's Center for Veterinary Medicine. The sections of the regulation specified in this rule, specifically 21 CFR 1.74(a)(1), 1.75(a), and 1.78(d), have been revised to change the reference from section 510(b) of the FD&C Act to section 510 of the FD&C Act, which is the correct statutory citation. The rule does not impose any new regulatory requirements on affected parties. The amendments are editorial in nature and should not be construed as modifying any substantive standards or requirements.

III. Notice and Public Comment

Publication of this document constitutes final action of these changes under the

Administrative Procedures Act (APA) (5 U.S.C. 553). Section 553 of the APA exempts "rules of agency organization, procedure, or practice" from proposed rulemaking (i.e., notice and comment rulemaking) (5 U.S.C. 553(b)(3)(A)). Rules are also exempt when an Agency finds "good cause" that notice and comment rulemaking procedures would be "impracticable, unnecessary, or contrary to the public interest" (5 U.S.C. 553(b)(3)(B).)

FDA has determined that this rulemaking meets the notice and comment exemption requirements in 5 U.S.C. 553(b)(3)(A) and (B). FDA's revisions make technical or non-substantive changes that pertain solely to ensuring that the regulations accurately cite the FD&C Act. FDA does not believe public comment is necessary for these minor revisions.

The APA allows an effective date less than 30 days after publication as "provided by the agency for good cause and published with the rule" (5 U.S.C. 553(d)(3)). A delayed effective date is unnecessary in this case because the amendments do not impose any new regulatory requirements on affected parties. As a result, affected parties do not need time to prepare before the rule takes effect. Therefore, FDA finds good cause for the amendments to become effective on the date of publication of this action.

List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, 21 CFR part 1 is amended as follows:

PART 1--GENERAL ENFORCEMENT REGULATIONS

1. The authority citation for part 1 continues to read as follows:

Authority: 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 342, 343, 350c, 350d, 350e, 350j, 350k, 352, 355, 360b, 360ccc, 360ccc-1, 360ccc-2, 362, 371, 373, 374, 379j-31, 381, 382, 384, 384a, 384b, 384d, 387, 387a,

387c, 393; 42 U.S.C. 216, 241, 243, 262, 264, 271; Pub. L. 107-188, 116 Stat. 594, 668-69; Pub. L. 111-353, 124 Stat. 3885, 3889.

2. Revise the third sentence of § 1.74(a)(1) to read as follows:

§ 1.74 Human drugs.

* * * ** *

(a) * * *

(1) * * *The unique facility identifier is the identifier submitted by a registrant in accordance with the system specified under section 510 of the Federal Food, Drug, and Cosmetic Act. * * *

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3. Revise the third sentence of § 1.75(a) to read as follows.

§ 1.75 Animal drugs.

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(a) * * *The Unique Facility Identifier is the identifier submitted by a registrant in accordance with the system specified under section 510 of the Federal Food, Drug, and Cosmetic Act. * * *

* * * ** *

4. Revise the last sentence of § 1.78(d) to read as follows.

§ 1.78 Biological products, HCT/Ps, and related drugs and medical devices.

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(d) * * *The unique facility identifier is the identifier submitted by a registrant in accordance with the system specified under section 510 of the Federal Food, Drug, and Cosmetic Act.

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Dated: March 25, 2021.

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Xavier Becerra,

Secretary, Department of Health and Human Services.

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